DELIVERY SYSTEMS AND METHODS FOR GASTRIC REDUCTION

Reference to Related Applications

[0001] This application claims priority from United States Provisional Patent Application No. 60/433,065, filed December 11, 2002, which is incorporated herein by reference in its entirety.

Field of the Invention

[0002] The present invention relates to methods and apparatus for reducing the effective cross-sectional area of a gastro-intestinal ("GI") lumen.

Background of the Invention

[0003] Morbid obesity is a serious medical condition pervasive in the United States and other countries. Its complications include hypertension, diabetes, coronary artery disease, stroke, congestive heart failure, multiple orthopedic problems and pulmonary insufficiency with markedly decreased life expectancy.

[0004] Several surgical techniques have been developed to treat morbid obesity, e.g., bypassing an absorptive surface of the small intestine, or reducing the stomach

size. These procedures are difficult to perform in morbidly obese patients because it is often difficult to gain access to the digestive organs. In particular, the layers of fat encountered in morbidly obese patients make difficult direct exposure of the digestive organs with a wound retractor, and standard laparoscopic trocars may be of inadequate length.

[0005] In addition, previously known open surgical procedures may present numerous life-threatening post-operative complications, and may cause atypical diarrhea, electrolytic imbalance, unpredictable weight loss and reflux of nutritious chyme proximal to the site of the anastamosis. Further, the sutures or staples that are often used in these surgical procedures may require extensive training by the clinician to achieve competent use, and may concentrate significant force over a small surface area of the tissue, thereby potentially causing the suture or staple to tear through the tissue.

[0006] In view of the aforementioned limitations, it would be desirable to provide methods and apparatus for achieving gastric reduction by reconfiguring the GI lumen of a patient.

[0007] It also would be desirable to provide methods and apparatus for gastric reduction including various end effectors that facilitate gastric reduction.

[0008] It further would be desirable to provide methods and apparatus for gastric reduction using a delivery catheter having an obturator that facilitates delivery of biocompatible anchors.

[0009] It further would be desirable to provide methods and apparatus for gastric reduction using a delivery catheter having an ejection needle capable of housing and placing a plurality of anchors sequentially.

Summary of the Invention

[0010] In view of the foregoing, it is an object of the present invention to provide methods and apparatus for gastric reduction having various end effectors that facilitate gastric reduction.

[0011] It is another object of the present invention to provide methods and apparatus for gastric reduction using anchors that can be reconfigured from a reduced delivery profile to an expanded deployed profile.

[0012] It is an additional object of this invention to provide methods and apparatus for gastric reduction using a delivery catheter having an obturator that facilitates delivery of biocompatible anchors.

[0013] It is a further object of the present invention to provide methods and apparatus for gastric reduction using a delivery catheter having an ejection needle capable of housing and placing a plurality of anchors sequentially.

[0014] These and other aspects of the present invention are accomplished by providing a gastric reduction system including methods and apparatus for delivering a plurality of anchors on opposing sides of a gastro-intestinal lumen and then moving the anchors to approximate the opposing walls of the lumen.

[0015] One aspect of the present invention involves using a delivery catheter to narrow a cross-sectional area of a gastro-intestinal lumen. The delivery catheter comprises an elongate torqueable tube, a needle translatably disposed within the torqueable tube and an anchor translatably disposed within the needle. The delivery catheter may include a stabilization device such as a coil screw to facilitate anchor delivery. According to some embodiments, the coil screw is fixedly attached to a distal end of the torqueable tube and the individual

coils form a central opening for the passage of the needle. In another embodiment, the coil screw is translatably disposed within a delivery catheter lumen.

[0016] In a further embodiment, the stabilization device comprises a shaft coupled to a plurality of resilient fingers and disposed within a delivery catheter lumen. The resilient fingers are adapted to automatically expand into a deployed configuration upon exiting the delivery catheter. Alternatively, the stabilization device comprises a plurality of resilient wires disposed within lumens spaced apart around the periphery of the torqueable tube. The resilient wires preferably are curved such that they extend radially outward from the distal tip of the torqueable tube when in a deployed configuration.

[0017] In still further embodiments, the needle is curved such that initial deployment of the needle through the coil screw causes the needle to penetrate the tissue wall such that a distal tip of the needle moves from a first side of the tissue wall to a second side of the tissue wall. Further deployment of the needle through the coil screw causes the needle to penetrate the tissue wall for a second time such that the distal tip of the needle moves from the second side of the tissue wall back to the first side of the tissue wall. The anchor then is ejected through the needle after the distal tip of the needle penetrates the tissue wall for the second time.

[0018] According to another aspect of the present invention, the delivery catheter includes an obturator comprising an elongate shaft translatably disposed within the torqueable tube. Advantageously, a plurality of anchors may be disposed about the shaft of the obturator. The obturator includes a sharpened distal tip adapted to be extended beyond the distal end of the torqueable tube

to facilitate the penetration of tissue wall. Alternatively, the obturator may have a blunt, spring-loaded tip extending distally from a sharpened distal tip so that the blunt, spring-loaded tip extends beyond the sharpened distal tip after the tip penetrates within a cavity.

[0019] According to a further aspect of the present invention, the delivery catheter comprises an ejection needle having an actuator cable, a first lumen housing a plurality of anchors, a second lumen and a spring-loaded shifting element for shifting the anchors from the first lumen to the second lumen. Pulling the actuator cable in a proximal direction causes an anchor to be shifted from the first lumen to the second lumen. The delivery catheter further comprises a push rod for ejecting the anchor from the ejection lumen.

Brief Description of the Drawings

[0020] The above and other objects and advantages of the present invention will be apparent upon consideration of the following detailed description, taken in conjunction with the accompanying drawings, in which like reference characters refer to like parts throughout, and in which:

[0021] FIG. 1 is a schematic view of an illustrative delivery catheter for use with the gastric reduction methods of the present invention;

[0022] FIG. 2 is a side-sectional view of the delivery catheter of FIG. 1, loaded with an anchor of the present invention, penetrating a GI tissue wall of a patient;

[0023] FIG. 3 is a perspective view of the handle of the catheter of FIGS. 1 and 2;

[0024] FIGS. 4A and 4B are views of one preferred embodiment of an anchor of the present invention in the reduced delivery state;

[0025] FIGS. 5A-5C are side views depicting transmural implantation of the anchor assembly of FIGS. 4A-4B;

[0026] FIG. 6 is a perspective view of a fastener suitable for use with the anchors of the present invention;

[0027] FIGS. 7A-7E are cross-sectional views depicting methods of using the gastric reduction system of the present invention;

[0028] FIG. 8 is a side view of a delivery catheter having a slotted torqueable tube constructed in accordance with the present invention;

[0029] FIGS. 9A-9D are side views of an obturator suitable for use with a delivery catheter of the present invention;

[0030] FIG. 10 is a sectional view of an alternative obturator suitable for use with a delivery catheter of the present invention;

[0031] FIGS. 11A and 11B are cross-sectional views of an ejection needle suitable for use with a delivery catheter of the present invention;

[0032] FIG. 12 is a cross-sectional view depicting the use of a pliers assembly to crimp a fastener of the present invention;

[0033] FIG. 13 is a cross-sectional view depicting the use of a scissors assembly to cut sutures of the present invention;

[0034] FIGS. 14A and 14B are cross-sectional views depicting the use of a jaw assembly to create a tissue fold in accordance with the principles of the present invention;

[0035] FIGS. 15A and 15B are perspective and sectional views, respectively, of alternative delivery catheters of the present invention;

[0036] FIG. 16 is a sectional view of an alternative stabilizing device of the present invention;

[0037] FIGS. 17A and 17B are perspective views of an alternative stabilizing device of the present invention;

[0038] FIGS. 18A-18C are perspective views of an alternative delivery catheter featuring a curved needle according to the present invention.

Detailed Description of the Invention

Overview of a Preferred Gastric Reduction System

[0039] Referring to FIGS. 1-7, illustrative components of gastric reduction apparatus 10 in accordance with the principles of the present invention are described. As explained in detail hereinafter, apparatus 10 enables a clinician to treat obesity by approximating the walls of a gastro-intestinal lumen to narrow the lumen, thus reducing the area for absorption in the stomach or intestines. Gastric reduction system 10 comprises anchor delivery catheter 11, anchor 22, and suture tensioning assembly 50. The structure and operation of each of these components are described separately below.

A. Delivery Catheter

[0040] Referring now to FIGS. 1 and 2, an illustrative embodiment of delivery catheter 11 constructed in accordance with the principles of the present invention is described. Delivery catheter 11 comprises elongate torqueable tube 14 having lumen 15 and needle 16 disposed for translation within lumen 15. Torqueable tube 14 preferably is formed of braided stainless steel wire having TEFLON coating 17. Needle 16 includes lumen 18

and non-coring distal tip 19 that facilitates penetration of tissue wall **W**. Needle 16 preferably is configured to penetrate tissue wall **W** so that the tissue anchor, described below, may employ a substantially atraumatic distal tip.

[0041] Push rod 21 is disposed for translation within lumen 18, and is configured to eject anchor 22 (see FIG. 2) out of distal end 23 of the delivery catheter and through tissue wall **W**. Referring to FIG. 2, one or more sutures 43 are attached to anchor 22, and extend through lumen 18 of needle 16 so that the proximal ends of the sutures 43 extend out of the mouth of the patient.

[0042] To facilitate penetration of needle 16 into tissue wall **W**, delivery catheter 11 preferably includes a stabilization device in the form of coil 24 that may be engaged to tissue wall W to stabilize distal end 23 of delivery catheter 11 against the tissue during actuation of needle 16. Coil 24 preferably is attached at one end to distal end 23 of catheter 11 and terminates at the other end in sharpened tip 25. According to some embodiments, coil 24 and needle are coaxial such that coil 24 defines a central passage that permits needle 16 to be reciprocated therethrough.

[0043] Referring to FIG. 3, an illustrative handle 30 for controlling operation of delivery catheter 11 is described. Handle 30 comprises proximal portion 31 and distal portion 32. Distal portion 32 is coupled to elongate tube 14 so that rotation of knob 35 rotates coil 24 to engage wall **W** of the gastro-intestinal tissue, as illustrated in FIG. 2. Handle 30 further comprises slider buttons 36 and 37 for imparting translational movement to needle 16 and push rod 21, respectively.

[0044] In operation, after knob 35 has been rotated to engage coil 24 to tissue wall **W**, slider button 36 is

actuated to urge needle 16 distally to pass through coil 24 and penetrate wall **W**. Once needle tip 19 has penetrated the tissue wall, slider button 37 is actuated urge push rod 21 distally, thus ejecting anchor 22 from needle 16 on the distal side of tissue wall W. After the anchor assembly has been deployed, slider buttons 36 and 37 are retracted in the proximal direction to retract the needle and push rod back within elongate tube 14. Knob 35 may then be rotated in the opposite direction to release its engagement with tissue wall **W**.

B. Anchor

[0045] Referring now to FIGS. 4A and 4B, a preferred embodiment of anchor 22 constructed in accordance with the principles of the present invention is described. Anchor 22 comprises braided sleeve 40 coupled to proximal bushing 41 and distal bushing 42. One or more sutures 43 are coupled to distal bushing 42 and extend through bushing 41. Proximal bushing 41 may slide along the suture(s) relative to the distal bushing 42, so that braided sleeve expands radially outward. Accordingly, after anchor 22 is disposed through a tissue wall (as depicted in FIG. 2), application of tension to the sutures causes the anchor to transition from an elongate reduced delivery profile (FIG. 4a) to an expanded, substantially disk-shaped deployed profile (FIG. 4B).

[0046] Braided sleeve 40 preferably comprises a highly porous, compliant and high strength material composed of numerous individual monofilament elements. Suitable materials for the monofilament elements include polyester, nylon, TEFLON, polypropylene and combinations thereof. Braided sleeve 40 also may be formed from a shape memory metal, such as a Nickel-Titanium alloy. In addition, the porous braid structure may promote an

easily and uniformly absorbable structure for use in applications in which anchor 22 is not intended for permanent implantation. Conversely, the porous braid structure may promote tissue growth to enhance anchoring in applications in which anchor 22 is designed for permanent implantation.

[0047] Anchor 22 may be made by thermo-forming two ends of a short length of braided sleeve to form proximal and distal bushings 41 and 42. Alternatively, separate bushings may be glued, over-molded, soldered or welded onto the ends of a length of braided sleeve. Suture(s) 43 may be attached to distal bushing 42 at a fixture point comprising, for example, one or more holes 46 formed in the distal bushing. Alternatively, the sutures may be attached using an eyelet, adhesive or other suitable fastener.

[0048] FIGS. 5A-5C depict deployment of anchor 22 from the reduced delivery profile to the expanded deployed profile. In FIG. 5A, anchor 22 has been forced through tissue wall **W**, illustratively the stomach wall, via needle lumen 18. Once delivery catheter 11 is withdrawn, anchor 22 is left disposed through tissue wall **W** with untensioned sutures 43 extending into the patient's stomach *S*. Sutures 43 pass through the esophagus and extend from the patient's mouth where they may be manipulated by the clinician.

[0049] In FIG. 5B, sutures 43 are shown partially tensioned, so that proximal bushing 41 engages the distal surface of tissue wall **W**. Because the stomach wall comprises a tough, resilient material, contact between the expanded braided sleeve and distal surface of the tissue wall causes the braided sleeve to partially expand, rather than slip back into the stomach via the track left by needle 16. When further tension is applied

to sutures 43, distal bushing 42 is approximated toward proximal bushing 41, thereby causing braided sleeve 40 to expand in the radially to the substantially disk-shaped profile shown in FIG. 5C.

[0050] Alternatively, anchor 22 may be preformed to self-expand to disk-shaped profile to automatically upon ejection from lumen 18 of needle 16. Such a preset shape may be accomplished by coupling the anchor to a fixture (e.g., a mandrel) and heat setting the braided sleeve in the disk-shaped profile. For example, the bushings may be approximated and then retained in close proximity by a fixture, or the shape may be imposed by compressing the braid in a disk-shaped mold. The formed anchor and fixture then may be placed into an oven for a predetermined amount of time, and quenched or slowly cooled to room temperature.

C. Suture Tensioning Assembly

[0051] Referring now to FIG. 6, illustrative suture fastener 54 constructed in accordance with the principles of the present invention is described. Fastener 54 comprises collar 70 having body 71 and channel 72 through which sutures 43 may freely translate prior to crimping. Once fastener 54 is crimped, sutures 43 are restrained from further translation through channel 72, thus retaining a desired amount of tension on sutures 43. Optionally, body 71 may incorporate lining 74 to enhance friction between body 71 and suture 43, thereby reducing the risk of slippage.

[0052] FIGS. 7A to 7E illustrate the steps of one procedure using gastric reduction system 10 to treat obesity. In FIG. 7A delivery catheter 11 of FIGS. 1-3 is inserted through a patient's mouth, esophagus **E** and

stomach **S**. FIGS. 7B-7E depict cross-sectional views of the stomach taken along plane P of FIG. 7A.

[0053] FIG. 7B depicts a step in the which a pair of anchors 22 have been positioned through opposing tissue walls **W** of the stomach so that sutures 43 pass from each anchor through esophagus E and extend out of the patient's mouth. FIG. 7C depicts a step in which sutures 43 have been threaded through the channel of fastener 54. At this point, fastener 54 has not been crimped and may be freely translated along sutures 43 using a push rod. More particularly, tension is maintained in the sutures while push rod 58 is used to urge fastener 54 through patient's mouth and esophagus E and into the stomach.

[0054] FIG. 7D depicts a step in which fastener 54 is moved to a position approximately midway between anchors 22. Push rod 58 then is used to hold the fastener in place while additional tension is applied to the sutures, thereby causing opposing walls **W** of the stomach to bow inward toward one another. As depicted in FIG. 7E, the application of additional tension pulls the opposing tissue walls into proximity with each other, thereby narrowing the cross-sectional area of stomach **S**.

[0055] At this step in the procedure, fastener 54 is crimped to maintain the tension in sutures 43. The excess length of sutures 43 is cut and removed via the patient's mouth. Advantageously, narrowing of stomach **S** limits the amount of food the patient consumes by providing a feeling of satiety after only a small amount of food is ingested.

[0056] Alternatively or in addition, sutures 43 may comprise self-tightening materials that shrink over time, or materials such as nickel titanium or electroactive polymers that are pre-stretched so that the subsequent application of heat or electricity causes the sutures to

shorten. By way of example, if pre-stretched nickel titanium or electroactive polymeric sutures are used, heat from a radiofrequency device or hot water may be used after the procedure to induce the sutures to tighten. Tension may be controlled by the ability of the sutures to tighten to a specific load. Tension also may be maintained by tying a knot or fusing the sutures to each other via application of heat.

Alternative Delivery Catheter Embodiments Suitable for use with the Gastric Reduction System

[0057] As described above with respect to FIG. 1, the preferred delivery catheter 11 includes torqueable tube 14 formed of braided stainless steel wire. Referring now to FIG. 8, alternative delivery catheter 75 instead comprises torqueable tube 76 having a plurality of through-wall slots 77 formed therein to enhance flexibility of the tube, yet maintain torqueability. Other components of the delivery catheter, includind needle 16 and push rod 21, may be configured as described hereinabove for the embodiment of FIG. 1.

[0058] Preferably, torqueable tube 76 is made from stainless steel with a laser-cut slot pattern. The slot pattern may be a sinusoidal repeating pattern of slots perpendicular to the longitudinal axis of torqueable tube 76. Alternatively, the slot density may be increased near the distal end of torqueable tube to provide a flexible distal tip capable of retroflexing, yet maintain a high degree of torqueability.

[0059] Referring to FIGS. 9A-9D, the anchors of the present invention may be delivered using obturator 90 translatably disposed within a lumen of delivery catheter 91. In FIG. 9A, obturator 90 preferably includes elongated shaft 92 having sharpened distal tip 93 to

facilitate tissue penetration. In FIG. 9B, anchor 22 is shown disposed in the reduced delivery profile around obturator shaft 92, with suture 95 attached to the anchor at fixture point 96. Obturator 90 is disposed to reciprocate within the delivery catheter, so that the sharpened distal tip may be extended past the distal tip 94. Because obturator 90 has sharpened distal tip 93, the anchor need not include a sharpened end suitable for penetration.

[0060] With respect to FIG. 9B, to penetrate tissue wall W, obturator 90 is extended from delivery catheter 91 and until the distal tip of the obturator passes through the tissue wall along with anchor 22. Once the obturator and anchor have passed through tissue wall W, the obturator is retracted (FIG. 9D). At this point, anchor 22 either self-expands to the expanded deployed profile or is induced to expand by applying tension to suture 95. Contact between the expanded anchor and the tissue wall prevents the anchor from being retracted along with the obturator. Tension applied to suture 95 to approximate tissue further reinforces the expanded profile by pulling the bushings together.

[0061] Although obturator 90 of FIGS. 9 accepts only a single anchor, it will be apparent to one of skill in the art of instrument design that obturator 90 may be configured to accept a plurality of anchors without departing from the scope of the present invention. A push rod (such as push rod 21 of FIG. 1) translatably disposed within delivery catheter 91, and adjacent to the obturator shaft may be used to advance the anchors along the shaft.

[0062] Referring now to FIG. 10 and in accordance with an alternative embodiment, obturator 90 includes blunt, spring-loaded distal tip 100. When the obturator is

pushed against a tissue wall, blunt tip 100 is depressed within longitudinally disposed cavity 101 containing compression spring 102. Depressing the blunt distal tip also exposes the tissue to sharpened obturator tip 104, which punctures the tissue wall. Once the sharpened tip 104 penetrates the tissue wall, compression spring 102 ejects the blunt tip 100 from cavity 101, thereby shielding surrounding tissue from sharpened tip 104.

[0063] With respect to FIGS. 11A and 11B, an alternative embodiment of an ejection needle suitable for use with the delivery catheter of FIG. 1 and configured to house and deliver a plurality of anchors 22 is described. Ejection needle 108 comprises non-coring distal tip 109, ejection lumen 110 through which push rod 111 is slidably disposed, anchor lumen 114 for storing anchors 22, first compression spring 115 disposed proximally with respect to anchor lumen 114 and spring-loaded shifting element 116 for shifting individual anchors from the anchor lumen to the ejection lumen. Shifting element 116 is coupled to second compression spring 117 that biases the shifting element toward the ejection lumen. In addition, actuator cable 118 extends from the shifting element to a trigger located at the proximal end of catheter 108.

[0064] When the trigger is actuated, the actuator cable is pulled proximally. This caused shifting element 116 to overcome the force exerted by compression spring 117 and move away from ejection lumen 110. Retraction of shifting element 116 against compression spring 117 permits anchor 22a to slide distally out of lumen 114 (under the urging of compression spring 115), so that anchor 22a is disposed substantially directly beneath shifting element 116 in the path of push rod 111 (FIG. 11A). When the trigger is released, compression spring

117 forces the shifting element 116 and anchor 22a toward ejection lumen 110. Once the anchor is pushed into ejection lumen 110, push rod 111 is used to eject anchor 22a from distal tip 109.

[0065] With respect to FIGS. 12-14, various end effectors suitable for use with the delivery catheter of FIG. 1 are described. Referring again to FIGS. 7A-7E, after sutures 43 have been threaded through fastener 54 and push rod 58 has been used to approximate the tissue walls, fastener 54 is crimped to hold the approximated tissue walls in place. Sutures 43 then are cut.

[0066] FIG. 12 illustrates pliers assembly 120, comprising arms 121 arranged to articulate about pivot point 122, which may be used to crimp fastener 54 and thereby retain sutures 43. Pliers assembly 120 is used to grip and crimp fastener 54 by manipulating an actuator disposed generally at the proximal end of catheter 11. After pliers assembly 120 is used to crimp fastener 54, it is retracted and scissor assembly 125 is advanced through catheter 11.

[0067] FIG. 13 depicts the use of scissors assembly 125, comprising blades 126 arranged to articulate about pivot point 127, to cut unneeded lengths of sutures 43 after fastener 54 has been crimped. Scissor assembly 125 is manipulated into cutting position and used to cut the sutures using an actuator disposed generally at the proximal end of catheter 11. Once sutures 43 have been cut, scissor assembly 125 is retracted through delivery catheter 11.

[0068] Referring now to FIGS. 14A and 14B, jaw assembly 130 is described for use in creating a tissue fold or to grab and hold tissue wall **W** during anchor delivery. Jaw assembly 130 comprises pair of jaws 131 arranged to rotate about pivot point 132. FIG. 14A

illustrates that jaw assembly 130 may be articulated into position adjacent a tissue wall using an actuator disposed generally at the proximal end of delivery catheter 11. In FIG. 14B, jaw assembly 130 is depicted grabbing tissue wall **W** to create fold **F** in the tissue wall. Advantageously, creation of fold **F** facilitates the penetration of tissue wall by needle 16 and subsequent delivery of anchor assembly 22 to the opposing side of the tissue wall.

[0069] Referring to FIG. 15A, delivery catheter 11 of FIG. 1 may be configured so that needle 16 exits a lumen offset from coil screw 24. In operation, coil screw 24 is threaded into the tissue wall and retains the delivery catheter in engagement with the tissue wall while needle 16 is pushed through the tissue wall. Delivery catheter 11 may further comprise additional lumen 135 dimensioned for the passage of an endoscope, per se known in the art. Alternatively, coil screw 24 may be translatably disposed within lumen 135 (FIG. 15B), rather than mounted to a distal end of the delivery catheter.

[0070] With respect to FIGS. 16 and 17 additional alternative embodiments of stabilization devices 138 suitable for use with the delivery catheter of the present invention are described. Stabilization device 138 of FIG. 16 comprises shaft 140 disposed within lumen 135 and includes resilient fingers 142 attached thereto. When shaft 140 is moved distally, fingers 142 exit lumen 135 and self-expand to a deployed configuration. Fingers 142 then may be manipulated to create a tissue fold by grasping and pulling a tissue wall using an actuator disposed generally at the proximal end of the delivery catheter.

[0071] Stabilization device 138 of FIGS. 17A and 17B comprises a plurality of resilient curved wires 144

disposed within lumens 145 and spaced apart around the periphery of lumen 135. Curved wires 144 are connected to an actuator located generally at the proximal end of the delivery catheter. Actuation of the actuator causes curved wires 144 to be either extended from or retracted into lumens 145.

[0072] Illustratively, curved wires 144 of FIGS. 17 extend radially outward when extended from lumens 145. Alternatively, curved wires 144 could extend radially inward at an oblique angle, so as to assume a partial corkscrew shape. During use, stabilization device 138 (including curved wires 144) is brought into contact with a tissue wall. Then, the wires are extended until they pierce and stabilize the tissue wall for anchor delivery.

[0073] **(start here)** With respect to FIGS. 18A-18C, another alternative embodiment of a delivery catheter constructed in accordance with the principles of the present invention is described. Delivery catheter 11 of FIGS. 18 comprises coil screw 24 and curved needle 150. In addition, endoscope 151 may be provided to visualize the site and aid in anchor delivery. Referring to FIG. 18A, once coil screw 24 has been screwed into tissue wall **W**, curved needle 150 is deployed through coil screw 24 such that needle 150 penetrates tissue wall **W** at first location **W1**. As the needle 150 is deployed from the distal tip of catheter 11, it curves outwardly such that full deployment results in the needle curving around and penetrating tissue wall **W** at second location **W2**. In other words, initial deployment of curved needle 150 through the coil screw causes the needle to penetrate the tissue wall (at **W1**) such that distal tip 152 of the needle moves from first side **S1** of the tissue wall to second side **S1** of the tissue wall.

[0074] Further deployment of needle 150 through the coil screw causes the needle to penetrate the tissue wall for a second time (at **W2**) such that distal tip 152 moves from the second side of the tissue wall back to the first side of the tissue wall. Referring to FIG. 18B, anchor assembly 22 is ejected through the needle after distal tip 152 penetrates the tissue wall for the second time. After ejecting anchor assembly 22, the needle is retracted. Referring to FIG. 18C, tensioning of the suture 43 produces fold **F** in tissue wall **W** between first location **W1** and second location **W2**.

[0075] Although preferred illustrative embodiments of the present invention are described above, it will be evident to one skilled in the art that various changes and modifications may be made without departing from the invention. It is intended in the appended claims to cover all such changes and modifications that fall within the true spirit and scope of the invention.